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⑤④ **Lung ventilator device.**

⑤⑦ Ventilation to a patient is provided in response to patient effort. The free flow of gas from a piston, or similar air source, in response to patient inhalation is detected, the instantaneous rate and volume of flow are measured and the measurements are used as control signals to a drive motor for the piston to move the piston to generate a pressure which is proportional to the sum of measured and suitably amplified rate and volume of flow signals. Since the command signal to the pressure generator only changes subsequent to, and not in advance of, a change in flow and volume, the ventilator is subservient to the patient and provides a proportional assist to patient ongoing breathing effort during inspiration (Proportional Assist Ventilation, PAV).

The present invention relates to a method and device to assist in ventilating the lungs of a patient in proportion to patient effort.

Ventilators are devices which are used to force gases, usually air or oxygen-enriched air, into the lungs of patients who, for one reason or another, are incapable of sustaining adequate ventilation entirely through their own efforts. The source of pressure may be a piston device, a built in blower or a high pressure line. Commercially-available ventilators utilize various mechanisms to regulate the pressure applied to the patient. In all cases, a breath is triggered which sets in motion a sequence of events during which pressure is applied until a volume or pressure target is reached, at which time the pressure cycle ends. Once the cycle is triggered, the ventilator proceeds in a predetermined manner, set by adjustments of dials on the control panel of the unit. With available devices and methods of ventilation, the ability of the patient to modulate breathing output through his own effort is limited or non-existent, as is apparent from the description below.

One of the principal indications for institution of ventilatory support is the presence of an unfavourable relation between patient effort and resulting ventilation (see Figure 1). This may be because of neuromuscular weakness, necessitating a greater effort to produce a given pressure, abnormal respiratory mechanics with which greater pressure output is desired to attain a given ventilation, or both. This abnormal relation impairs the patient's ability to control ventilation and breathing pattern in a way that insures optimal CO₂ removal and/or oxygenation. In addition, the high respiratory effort results in distress and, if the effort is sufficiently high, may ultimately lead to exhaustion (i.e. respiratory muscle fatigue).

By providing positive pressure at the airway during inspiration, all current approaches to ventilatory support (volume-, pressure- or time-cycled approaches) unload the respiratory muscles and improve the relation between patient effort and achieved ventilation in a global sense. For a given inspiratory effort, the patient receives a greater volume in the assisted breath than he would otherwise. The price of this support, however, is a variable degree of loss of control by the patient over his ventilation and breathing pattern. These effects are illustrated in Figures 2 to 4.

With volume cycled ventilation (Fig. 2), the ventilator delivers pressure in whatever amount and time pattern is necessary to cause a predetermined flow pattern and tidal volume to be achieved during the assisted breath. The operator of the ventilator (i.e. physician or therapist), and not the patient, determines the flow and volume to be delivered. If the patient makes an inspiratory effort during the inhalation phase, the ventilator simply decreases the pressure it provides in such a way that the flow and

volume delivered are the same as prescribed. The more inspiratory effort the patient makes, the less the pressure delivered by the ventilator (Fig. 2, left to right). Conversely, if the patient does not wish to receive the prescribed volume or flow, and fights back, the machine generates a greater pressure to offset the patient's opposing effort. There results, therefore, an antagonistic relation between patient and machine.

With this volume cycled method of ventilation, the degree of loss of patient control over his own breathing varies, depending on the type of ventilation used. With continuous mandatory ventilation (CMV), loss of patient control is complete, as he not only cannot alter flow and volume within each assisted breath, but also cannot influence frequency. In the assist/control mode (A/C), the patient can alter the frequency of the mandatory breaths, but within each breath, the same adverse relation between patient effort and pressure delivered applies. With the newer synchronized intermittent mandatory ventilation (SIMV), spontaneous breaths are permitted between the mandatory breaths. During these breaths, the patient controls the rate and depth of breathing. However, the abnormal relation between effort and ventilatory output (see Fig. 1) which was the reason for installation of ventilatory support in the first place, continues to apply. In fact, it is worsened by the additional load imposed on the patient by the device and endotracheal tube. The patient, therefore, alternates between breaths in which effort is entirely without ventilatory consequence (mandatory breaths), and breaths in which effort produces abnormally low ventilatory return.

With pressure support methods of ventilatory assist (PS), the delivered pressure is a predetermined function of time, usually an intended square wave pressure beginning at the onset of inspiration and terminating as flow rate declines to a specific amount. The pressure delivered is, therefore, independent of how much inspiratory effort the patient is making during inspiration (see Figure 3). Any inspiratory effort the patient makes during the breath would produce greater flow and volume (Figure 3, A to C). However, since the pressure delivered is independent of effort, the ventilatory consequences of patient effort are still subject to the abnormal relation between effort and lung expansion dictated by the disease (Figure 1). Although the overall relation between effort and ventilation is improved, the ability of the patient to alter ventilation in response to varying needs continues to be impaired. Furthermore, since patient effort normally increases in a ramp fashion during inspiration, while pressure delivered by the ventilator is nearly constant, the ventilator overassists early in inspiration while the assist decreases relatively as inspiration progresses. The patient then would sense an increase in load as inspiration is lengthened and this

prompts the patient to breathe with short inspirations, resulting in a small tidal volume.

With airway pressure release ventilation (APRV), pressure at the airway alternates between high and low levels with a time sequence that is independent of patient effort (see Figure 4). The periodic cycling of pressure insures a minimum ventilation. The patient can also obtain spontaneous breaths independent of the programmed cycles. During these, he receives no assist (i.e., similar to SIMV). The relation between effort and ventilatory consequences during these breaths continues to be poor, as dictated by disease, limiting the patient's ability to alter flow and ventilation in response to varying needs. In fact, since with APRV, operating lung volume is increased, the relation between effort and ventilatory consequences is further compromised on account of the well established adverse effect of increased lung volume on neuromechanical coupling (i.e. pressure generation for a given muscle activation).

We are aware of specific prior art proposals to effect modifications to commercially-available pressure-powered ventilators to allow the pressure produced to vary with electrical activity recorded from a respiratory nerve, as described in Remmers et al, "Servo Respirator Constructed from a Positive-Pressure Ventilator", J. Appl. Physiol. 41: 252 to 255, 1976. To the extent that activity in inspiratory nerves reflects effort these modifications would permit a ventilator to deliver pressure in proportion to effort, as is intended in the present invention. These modifications, which were developed for animal use where inspiratory nerves are accessible and can be recorded from, implicitly require direct measurement of inspiratory muscle or nerve activity which is not practical in humans requiring ventilatory support. In contrast, the present invention permits the delivery of pressure in proportion to patient effort without the need for direct recording of activity, and through the use of algorithms that permit the inference of degree of effort from easily measurable variables, such as flow and volume. Poon et al, "A Device to Provide Respiratory Mechanical Unloading", IEEE Trans. Biomed. Eng. 33: 361 to 365, 1986, described a modification to a commercially-available volume ventilator which permits the ventilator to deliver pressure in proportion to inspired flow. Although this device was developed originally to simulate and amplify the effect of helium in reducing respiratory resistance during experimental studies on exercising humans, it can theoretically be used in patients to provide partial ventilatory support. As such, the device would develop pressure with a time pattern that resembles inspiratory flow, which is highest early in inspiration and declines later. Since this pattern is poorly (or even negatively) correlated with patient inspiratory effort, which rises continuously during the inspiratory phase, this pattern of support is quite unlike the method of the

present invention, where pressure is intended to be a function of inspiratory effort throughout inspiration, as described in more detail below. Not only is the method completely different (simple resistive unloading vs assist in proportion to effort) but the apparatus described herein is much more suitable for our method (Proportional Assist Ventilation, PAV) than a modification of existing volume ventilators which are designed to regulate flow and not pressure. The design of the invention permits unlimited flow and there is no delay between onset of inspiratory effort and onset of flow from ventilator to patient, since no triggering is required before the gas delivery system is communicated to the patient. The system of the invention also can effect proportional assist through positive pressure at the airway or negative pressure at body surface, whereas a modified positive pressure, gas powered ventilator can serve the former function only.

Some known prior art patents describe a variety of breathing devices. U.S. Patent No. 3,985,124 describes a spirometer for measurement of the rate and volume of expiratory breathing to create a graphic record of the same. This device possesses an expandible chamber of the piston type which expands in proportion to the exhaled air.

U.S. Patent No. 3,669,097 describes a device for increasing the capacity and strength of lungs. An expandible bellows chamber is connected to a conduit having a mouthpiece. A selectively-adjustable valve is present in the conduit for constricting the passage from the mouthpiece to the inlet to the bellows chamber, so that a force in excess of the normal pressure developed by the lungs is required to expand the bellows.

U.S. Patent No. 4,301,810 describes a ventilatory muscle training apparatus comprising a reservoir and a mouthpiece and also having a simple valving system to vent stale air from the reservoir during exhalation and let fresh air into the reservoir during inhalation. The air flow through the mouthpiece is monitored to ensure the intended manner of use of the apparatus is maintained.

U.S. Patent No. 4,462,410 describes a recording spirometer for performing a breath test which uses a movable pusher plate which is moved in response to the breathing of the patient and a recording medium which enables a record to be made of the volume of air expelled by a patient as a function of time.

U.S. Patent No. 4,487,207 describes a lung exercise device which has a mouthpiece through which a patient inhales. A conduit connects the conduit to an air inlet and a valve is located in the conduit, normally biased to a closed position. Upon inhaling, the valve is opened and the amount of air inhaled is monitored.

U.S. Patent No. 4,459,982 by Fry discloses a lung ventilator device which comprises a chamber means which delivers respiratory gases to a patient. This patent describes, as one embodiment, the provision

of a flow rate directly controlled by the patient's instantaneous demand under spontaneous breathing of the patient, and hence, at first sight, may be considered relevant to the present invention. However, the operation of the device and its control require movement of the piston in the chamber to maintain the pressure at the patient's airway constant and equal to a reference pressure determined by the operator. Since the device operates to maintain airway pressure constant throughout inspiration, it is apparent that it does not deliver pressure in proportion to patient effort (which varies throughout inspiration), as is the case of the present method (PAV).

British Patent No. 1,541,852 describes a piston, driven by a motor which alters the pressure in the piston according to the power supplied to motor. This system is designed to deliver pressure according to a predetermined pressure-time profile (as in pressure cycled ventilators) or to force a given volume of gas into the patient (as in volume cycled methods). In the method of the present invention, neither pressure nor flow and volume is/are predetermined. Rather, the patient determines his own flow pattern and tidal volume through his own effort, while the ventilator delivers pressure in a manner that parallels the patient's on-going effort (which is obviously not predetermined).

Other representative prior art employing motor driven pistons that deliver predetermined pressure vs time or volume vs time patterns know to the applicant are Hillman, U.S. Patent No. 4,036,221, Chu, U.S. Patent No. 4,617,637 and Apple, U.S. Patent No. 4,726,366.

Stawitcke (U.S. Patent 4,448,192, U.K. Patent No. 2,121,292) describes a system with motor driven pistons and extremely complex controls, the intent of which are to reduce conflict between patient and ventilator. A control system continuously computes an ideal pressure-volume trajectory designed to cause the ventilator to deliver gas in the amount (tidal volume) and flow rate specified by the physician while allowing for different degrees of patient effort. Although this system permits the patient to over-ride physician-specified delivery pattern within an inhalation or over a brief period, the control system readjusts the terms in the equation, so that physician-determined criteria are ultimately met. The principle of control is, therefore, similar to volume-cycled methods, in that an increase in patient effort is met with a decrease in machine assist to return ventilator output to what the physician prescribes. The main difference from other volume-cycled methods is in the freedom the patient is accorded to transiently over-ride the prescriptions by the physician. This principle of operation is diametrically opposite to that executed by the method of the present invention. Thus, in the Stawitcke system, the physician sets targets for volume, flow and timing and the machine

alters the various parameters in the control system equation in such a way as to meet physician requirements. By contrast, in the present invention, the proportionalities between pressure, on one hand, and volume and flow on the other hand are the parameters that are predetermined, while the patient is left entirely free to select volume, amount and pattern of flow, and timing of each breath.

It will be apparent from this discussion, that prior art patient ventilation systems provide ventilatory support to a patient in accordance with parameters which are determined mainly by a physician and not by the patient. Generally, the prior art has required some target flow rate, target pressure, target volume, and/or target frequency or inspiratory or expiratory time. Such requirements give rise to the various problems discussed above.

The present invention is directed to a quite different approach to ventilatory support from those of the prior art described above. In the present invention, the pressure delivered by the ventilator increases in direct proportion to patient effort, and the proportionality applies from breath to breath, as well as continuously throughout each inspiration. In effect, patient effort is amplified, thereby normalizing the relation between effort and ventilation, while leaving the patient entirely in control of all aspects of his breathing. In the present invention, the pressure delivered by the ventilator to the patient reflects the amplitude as well as the time pattern of patient effort (see Figure 5). There is no target flow rate, no target pressure, no target volume, and no target frequency or inspiratory or expiratory time, as there is in the prior art. These parameters are determined solely by the pattern of patient effort and the ventilator simply amplifies the ventilatory consequences. The net effect of this approach is that the abnormal relation between effort and ventilatory consequences is restored towards normal, returning the patient's ability to alter ventilation and flow pattern, as dictated by his own varying needs, including the optimization of respiratory sensation. The ventilation procedure of the present invention may be termed proportional assist ventilation (PAV).

In the left-hand graph in Figure 6, there is provided a summary of the relation between patient effort and pressure delivered by the ventilator with different ventilatory methods, while the right-hand graph shows the relation between patient effort and ventilatory consequences. With SIMV, PS, and APRV, there is a minimum ventilation in the absence of effort. Any influence the patient may have on his breathing is subject to the limitation imposed by disease (the slope of the line with SIMV, PS and APRV is similar to the of the disease line). With PAV, in contrast, the relation between effort and ventilatory consequences is normalized at different levels of effort.

In accordance with one aspect of the present invention, there is provided a novel type of lung ven-

tilator apparatus which delivers PAV with a relatively simple electrically-powered operation. In the present invention, the gas pressure at the patient's airway is determined by the action of an electric motor acting on a piston reciprocating in a chamber in relation to any desired command input. The electrical motor moves the piston with a force proportional to the magnitude of the power applied to the motor. On-going rate of flow (\dot{V}) and volume of flow (V) of gas moving from chamber to patient are monitored with electronic circuitry that permits the independent adjustment of the gain or amplifications of each of the two signals. The electronic circuitry provides electric power to the motor in proportion to the sum of the suitably amplified V and \dot{V} signals. As is described in more detail below, this procedure causes the device to provide pressure in proportion to patient effort.

The difference between proportional assist ventilation and other modalities is that the patient has total control over his breathing pattern. In this modality, the apparatus works on the principle of positive feedback, namely the more volume and flow the patient takes, the more pressure the machine provides. The adjustable parameter is not a target pressure or a target volume, but a degree of assist (or proportionality) to the patient's breathing pattern. Thus, if the patient's respiratory system stiffness (elastance) is such that it requires 40 cmH₂O per litre of inflation, the machine may be adjusted to provide a specified amount of pressure/unit of inhaled air. If in this case, the proportionality is set to 20 cmH₂O/L, the patient has to do half the elastic work and the machine does the other half, and so on. There is no requirement that the patient take in a certain volume or reach a certain pressure. As soon as the patient decreases his own effort, air stops flowing in and the machine stops pumping.

Accordingly, in one aspect of the present invention, there is provided a method for providing breathing assistance in proportion to patient ongoing inspiratory effort, which comprises providing a free flow of gas from a gas delivery system to a patient in response to a pressure gradient generated by patient inspiratory effort; determining the rate and volume of flow of the gas to the patient; independently amplifying signals corresponding to the determined rate and volume of flow; and providing a pressure assist to the gas in proportion to the sum of the determined and amplified rate and volume of flow.

The present invention also provides apparatus for delivering proportional assist ventilation to a patient, comprising means for delivering a free flow of gas to the patient in response to patient inhalatory effort; means operatively connected to the gas delivery means for generating pressure in the free flow of gas in response to an electrical command signal; detection means for detecting the instantaneous volume and rate of gas flow to the patient and for generating a separate electrical signal corresponding in mag-

nitude to each of the detected values; means for selectively applying amplification to each of the electrical signals; and means for generating the electrical command signal to the pressure generating means in proportion to the sum of the amplified electrical signals corresponding in magnitude to the instantaneous rate and volume of flow.

There are several advantages to this type of ventilation, in relation to the prior art ventilation devices and modalities.

The first advantage is one of comfort, in that the relation between machine and patient is not only synchronous, but entirely harmonious. There is no fighting between patient and machine, and, in fact, the ventilator becomes an extension of the patient's own muscles. Since with PAV pressure is only delivered if patient effort is present, and the pressure is proportional to patient effort throughout inspiration, the patient must contribute a fraction of the pressure used to expand the patient's chest. The ventilator needs to deliver less pressure for a given tidal volume, as compared with other devices. With other forms of ventilation, patient contribution cannot be relied upon and often patient contribution is antagonistic. The required peak airway pressure is higher with such devices than in the present invention. In preliminary studies, with the ventilation procedure of the invention, it was found that peak airway pressure with PAV was only one-third to one-half that with SIMV at the same level of ventilation. Since the required peak pressure is lower in the present invention, it is possible to ventilate some patients through a nose or face mask and avoid intubation altogether. Intubation, directly or indirectly, is one of the main causes of morbidity and mortality in ventilated patients.

Intrathoracic pressure remains negative during inspiration, as in normal subjects, thereby reducing the hemodynamic complications of artificial ventilation. The greater comfort, lack of fighting and possible avoidance of intubation greatly reduces the need for sedation or paralysis of patients, both of which impair the patient's defenses.

With PAV, the ventilator is simply an extension of the patient's own muscles and is, hence, subject to all the intrinsic control mechanisms that adjust ventilation to varying needs and protect against various injuries. Such control mechanisms can potentially be of considerable benefit. For example, the respiratory system is endowed with powerful reflexes to protect the lungs from overdistension. Overdistension would reflexly cause inhibition of inspiratory effort and recruitment of expiratory effort. Since the ventilator ceases its pressure when inspiratory effort is terminated, overdistension would reflexly cause the ventilator to cycle off. The risk of barotrauma is reduced. Furthermore, a patient's metabolic needs may vary greatly from time to time as a result of movement, shivering or temperature changes. Normally, the res-

piratory control changes inspiratory effort so that ventilation matches metabolic demands. With PAV, such adjustments in inspiratory effort would be met by concordant changes in machine assist. This effect tends to control arterial blood gas tensions within narrow limits. Furthermore, the patient would not fluctuate from periods of overassist to underassist, and hence distress, as his metabolic demands change.

With the present invention, there is less likelihood of inspiratory muscle disuse because a minimum level of inspiratory muscle activity must be present with the PAV modality. If PAV is used throughout the illness, there would be no period in which the central control mechanisms are inactive (apnea). Central respiratory dysfunction is common in the weaning period and may be due, in part, to protracted inactivity of the respiratory centres produced by machine settings that promote apnea with other modalities of ventilatory support. The lesser likelihood of central and peripheral muscle dysfunction facilitates weaning.

An improved efficiency of negative pressure ventilation is achieved. The ability of negative pressure devices to reduce intrathoracic pressure is limited, making them quite ineffective in patients with severe mechanical abnormalities (e.g. chronic obstructive pulmonary disease [COPD] or pulmonary fibrosis). Furthermore, the lack of harmony between pump pressure and upper airway dilator muscle activity promotes airway collapse. If the negative pressure applied to a body surface is harmonized with patient's own inspiratory effort, upper airway narrowing is decreased and the combined pump and patient generated pressure may be adequate for ventilation. These two factors may make it possible to ventilate patients with severe lung disease during sleep using the present invention. At present, cuirass ventilation in these patients (e.g. COPD) is feasible only during wakefulness.

An essential and distinguishing feature of the procedure of the present invention is that the pressure generated by the ventilator follows the exchange of gas from machine to patient as opposed to leading or causing it, as in conventional devices. Flow and volume must first be altered before the ventilator alters its pressure output.

Although the ventilating apparatus of the invention was designed specifically for the purpose of delivering this proportional assist mode, the design principles used to accomplish this end also make it possible to use the machine, with very minor electronic additions, to deliver pressure in proportion to any desired input. This extreme versatility permits adaptations to fit future needs with minimal modification.

In this specification, reference is made to the accompanying drawings, in which:

Figure 1 is a graphical representation of patient effort and respiratory flow and volume;

Figure 2 is a graphical representative of volume cycled ventilation (VCV) according to one prior art procedure;

Figure 3 is a graphical representation of pressure support ventilation (PSV), according to another prior art procedure;

Figure 4 is a graphical representative of airway pressure release ventilation (APRV) according to a further prior art procedure;

Figure 5 is a graphical representative of proportional assist ventilation (PAV) according to the present invention;

Figure 6 is a graphical representative comparing proportional assist ventilation (PAV) in accordance with the present invention with prior art procedures;

Figure 7 shows a schematic of a device for providing proportional assist ventilation and a graphical representative of ventilator gain and patient elastance; and

Figure 8 is a schematic representative of a lung ventilator device for effecting proportional assist ventilation in accordance with another embodiment of the invention.

In the present invention, patient effort is detected and responded to. Inspiratory effort can be defined as the degree of inspiratory muscle activation (E_i) relative to the maximal possible activation (E_{max}). Inspiratory activity results in generation of inspiratory pressure (P_{musi}) according to the relationship:

$$[i.e. E_{max}] P_{musi} = fE_i/E_{max}$$

where f is the function that governs the conversion of activity to pressure. This function is primarily influenced by muscle strength, lung volume (V) and inspiratory flow (\dot{V}) (see Younes et al, A model for the relation between respiratory neural and mechanical outputs. I. Theory, J. Appl. Physiol 51:963-978, 1981, incorporated herein by reference). Since maximal inspiratory pressure is not affected by volume in the resting tidal volume range and flow at resting levels is associated with very small velocities of muscle shortening relative to the maximal possible velocity (Younes et al, supra), the function that governs the relation between effort and P_{mus} is primarily affected by muscle strength under resting levels of ventilation. This is very frequently abnormal in patients requiring ventilatory support because of primary neuromuscular disease, secondary to nutritional or metabolic derangements, or as a consequence of hyperinflation as in the case in patients with severe asthma or chronic obstructive pulmonary disease (COPD). Under these conditions, a given effort results in less than normal pressure and hence less expansion.

At any instant during the breath, the pressure applied to the respiratory system (P_{appl}) is dissipated against the elastic and resistive elements of the respiratory system, since inertial losses are negligible at resting levels of ventilation. Thus:

$$P_{\text{appl}} = P_{\text{el}} + P_{\text{res}}$$

where P_{el} is a function of lung volume above passive Functional Residual Capacity (FRC) ($P_{\text{el}} = fV$), as dictated by the pressure-volume relation of the respiratory system, and P_{res} is a function of flow, as dictated by the pressure-flow relation of the respiratory system. Although both functions may be complex and non-linear, linear functions are used in this discussion for convenience. Thus:

$$P_{\text{appl}} = V.E_{\text{rs}} + \dot{V}.R_{\text{rs}}$$

where V is the volume above ERC, E_{rs} is the elastance of the respiratory system in the linear range (in $\text{cmH}_2\text{O/l}$), \dot{V} is the flow rate and R_{rs} is respiratory system (including ventilating apparatus) resistance (in $\text{cmH}_2\text{O/l/sec}$).

During spontaneous breathing, the only source of P_{appl} is pressure generated by the respiratory muscles (P_{mus}). In patients attached to a ventilator, applied pressure is the sum of patient generated pressure and machine generated pressure (P_{vent}). The latter may take the form of positive pressure at the airway or negative pressure at a body surface (e.g. by tank or cuirass).

During supported ventilation, it follows that the instantaneous relation between the opposing forces is determined by the relationship:

$$P_{\text{mus}} + P_{\text{vent}} = V.E_{\text{rs}} + \dot{V}.R_{\text{rs}} \quad (1)$$

or

$$P_{\text{mus}} = V.E_{\text{rs}} + \dot{V}.R_{\text{rs}} - P_{\text{vent}} \quad (2)$$

Since V , \dot{V} and P_{vent} can be continuously measured and E_{rs} and R_{rs} can be measured or estimated, P_{mus} can be computed continuously, by any convenient computing device, from the measured values, and the ventilator device made to change pressure in proportion to the instantaneous P_{mus} .

$$P_{\text{vent}} = A.P_{\text{mus}}$$

where A is the proportionality between P_{vent} and P_{mus} in $\text{cmH}_2\text{O/cmH}_2\text{O}$.

A simpler and more versatile approach is to design the ventilator such that it delivers pressure according to the following equation:

$$P_{\text{vent}} = K_1 V + K_2 \dot{V} \quad (3)$$

where K_1 is a gain factor applied to the volume signal (in $\text{cmH}_2\text{O/L}$) and K_2 is a gain factor applied to the flow signal (in $\text{cmH}_2\text{O/L/sec}$). Although constants are used in this analysis, non-linear functions can be used where appropriate.

If A is the desired proportionality with P_{mus} and P_{mus} is given by equation (2) above, it follows that:

$$P_{\text{vent}} = A.V.E_{\text{rs}} + A.\dot{V}.R_{\text{rs}} - A.P_{\text{vent}}$$

so that

$$P_{\text{vent}} (1 + A) = A.E_{\text{rs}}.V + A.R_{\text{rs}}.\dot{V}$$

or

$$P_{\text{vent}} = [A/(1 + A)] E_{\text{rs}}.V + [A/(1 + A)] R_{\text{rs}}.\dot{V}$$

The latter equation has the same form as equation (3) above, where K_1 is a fraction (ie $A/(1+A)$) of respiratory elastance and K_2 is the same fraction of respiratory resistance. Accordingly, P_{vent} can be made

proportional to P_{mus} without actually having to calculate P_{mus} according to equation (2). Hence, if it is desired to produce a P_{vent} which is three times as much as P_{mus} ($A=3$), K_1 is set to be $0.75 E_{\text{rs}}$ and K_2 is set to be $0.75 R_{\text{rs}}$. It follows that either equation (2) or equation (3) can be used to control P_{vent} . However, the use of equation (3) is advantageous, for the following reasons.

With equation (2), P_{vent} is used to derive the command signal to the pressure generating mechanism, while being, itself, the controlled variable. Particularly in view of the inevitable lag between command signal and P_{vent} , this situation promotes oscillations which require elaborate filtration to avoid.

With equation (3), the use of individually adjustable gain factors for flow and volume permits unequal unloading of the resistive and elastic properties, which may have advantages in particular clinical situations. In addition, in many cases measurement of E_{rs} and R_{rs} are difficult to obtain or are unreliable, but with the use of equation (3), the gain factors for V and \dot{V} can be separately adjusted to patient comfort, thereby obviating the necessity of having to know E_{rs} and R_{rs} . An example of a system which operates in accordance with this principle is shown in Figure 11 and described below.

An essential and distinguishing feature of proportional assist ventilation (PAV) according to the invention, is that the pressure generated by the ventilator follows the exchange of gas from machine to patient, as opposed to leading or causing it. Flow and volume must first be altered before the ventilator alters its pressure output. Any device which delivers PAV to a patient, therefore, must permit free flow of air from the device to the patient in response to changes in pressure at the patient's end and this requirement is most readily exemplified by breathing from an easily-movable bellows.

Since, at any instant, the elastic and resistive pressure losses (right side of equation 1) are balanced by the sum of P_{mus} and P_{vent} , any increase in P_{mus} causes a change in total applied pressure and a corresponding change in flow and volume. The device then responds by changing its pressure, thereby causing a greater change in flow and volume.

A system that operates according to this sequence displays positive feedback. On its own, such a system is inherently unstable and tends to "run-away", since, as some air leaves the system, it generates pressure which causes more air to leave, causing the system to generate even more pressure, and so on. When attached to a patient, however, the positive feedback inherent to the ventilator is counteracted by the negative feedback provided by the mechanical properties of the patient, namely elastance and resistance.

Figure 7 schematically illustrates how the interaction between a PAV system and a patient tends to

eliminate the potential for "run-away" and causes the system to simply amplify the ventilatory consequences of patient effort. The upper portion of Figure 7 illustrates a simple design which satisfies the criteria of a PAV delivery system. The patient is attached to a freely-moving piston. Movement of air from the piston to patient is sensed by a flowmeter, resulting in flow and volume signals. The latter signals are used to activate a motor which applies force to the back of the piston in proportion to the flow and volume signals. Separate gain controls determine the proportionalities between flow and volume on the one hand and the force exerted, namely resulting pressure, on the other hand. Such gain volumes are analogous to the terms K_1 and K_2 in equation (3).

To facilitate description of the interaction between the patient and a PAV system, the hypothetical case will be considered where all changes (P_{mus} and P_{vent}) take place in discrete sequential steps, illustrated by the lower three graphs in Figure 7, and all generated pressure is applied against the elastance of the respiratory system (i.e. the resistance is zero). Patient elastance is expressed in arbitrary units and is assigned a value of one (i.e. 1 unit pressure/unit volume).

Before the onset of inspiration, i.e. $P_{mus} = \text{zero}$, the airway pressure and volume are stable, reflecting the level of positive expiratory pressure (zero in the illustrated case). Assume the patient makes a step change in P_{mus} of 4 units. According to patient elastance, four units of volume move from ventilator to patient. The airway pressure is still zero, as seen by the interval between the first pair of vertical lines. The transfer of gas (volume and flow), however, is sensed and causes the pressure in the system (i.e. P_{aw}) to increase according to the volume signal and the chosen gain factor. Assuming the gain factor is set at 0.5 units of pressure/unit of volume, the ventilator will increase P_{aw} by 2 units of pressure in response to the initial four units of volume, so that the total pressure ($P_{app} = P_{mus} + P_{aw}$) then has increased to six units, thereby causing two more units of volume to be transferred. This increased volume, in turn, is sensed and, according to the gain factor, causes P_{vent} to rise an additional one unit, which itself results in the transfer of one more unit of volume, and so on.

It can be seen that, because the gain factor is less than the elastance of the patient, the magnitude of the steps decreases progressively and, accordingly, there is no tendency to "run-away". In fact, if P_{mus} remains constant, the volume rises to an asymptote. This effect can be seen graphically in Figure 7, the volume asymptote is twice the value produced by the patient in the absence of assist.

With a larger step change in P_{mus} , for example the second step in Figure 7, the volume exchanged under the patient's own power is larger, and so is the response of the ventilator but, again, there is no tendency to runaway, and the volume exchanged in this second

step bears the same proportionality to P_{mus} as the smaller first step.

Since the elastic recoil at any instant is sustained jointly by patient and ventilator, if the patient decreases his contribution, as signified by the arrow in Figure 7, the pressure applied to the respiratory system, namely $P_{mus} + P_{vent}$, is no longer sufficient to sustain the system's elastic recoil. As in the case of spontaneous breathing, when P_{mus} decreases at the end of inspiration, a positive gradient develops from alveoli to airway and exhalation begins.

The extent of amplification of the elastic component of P_{mus} is a function of the gain on the ventilator volume signal (K_1) relative to the patient's own elastance (E_{rs}). Since the total elastic pressure ($V \cdot E_{rs}$) is balanced in part by the elastic component of P_{mus} ($P_{mus}(el)$) and in part by the elastic assist of the ventilator ($V \cdot K_1$), it follows that:

$$\begin{aligned} P_{mus}(el) &= V \cdot E_{rs} - P_{vent}(el) \\ &= V \cdot E_{rs} - V \cdot K_1 \\ &= V (E_{rs} - K_1) \end{aligned}$$

The ratio of total elastic pressure applied, namely $V \cdot E_{rs}$, to that developed by the patient ($P_{mus}(el)$), which is the elastic amplification factor ($F(el)$), therefore, is given by the equation:

$$F(el) = V \cdot E_{rs} / V (E_{rs} - K_1) = E_{rs} / [E_{rs} - K_1]$$

Hence, if K_1 is $\frac{1}{2}E_{rs}$, as in the example of Figure 7, then the amplification factor is 2. For $K_1 = 0.75 E_{rs}$, the amplification factor is 4, and so on. Where K_1 equals or exceeds E_{rs} , amplification would be infinite and a run-away situation would result. However, since E_{rs} increases progressively as lung volume increases, a run-away situation produced by the gain factor accidentally being higher than E_{rs} near functional residual capacity, would soon be aborted as lung volume increases and E_{rs} increases.

The example shown in Figure 7 is intended as an oversimplification to explain the principles involved in the present invention. For example, the resistance is never zero and part of P_{mus} is expended against the resistance elements of the system (patient plus equipment). However, similar analysis and consideration can be made to the resistance component of P_{mus} , i.e. $P_{mus}(res)$. At any instant, the total pressure used to offset the flow-related pressure gradient is given by $\dot{V} \cdot R$, where R is the total resistance for airflow from ventilator to chest wall and includes equipment resistance. This pressure is provided in part by the ventilator ($\dot{V} \cdot K_2$) and in part by the resistance component of P_{mus} ($P_{mus}(res)$). Using a similar analysis as that for elastic pressure, it can be shown that the amplification of the resistance component of P_{mus} ($F(res)$) is a function of the flow gain on the ventilator (K_2) relative to the total resistance (R), according to the relationship:

$$F(res) = R / [R - K_2]$$

Because volume rises gradually during inspiration whereas flow peaks early on and declines later

in inspiration, the partition of P_{mus} between elastic and resistance components varies greatly with inspiratory time. $P_{\text{mus}}(\text{res})$ contributes the largest fraction of P_{mus} early in inspiration with this fraction declining to nearly zero by the end of inspiration. The correlation between instantaneous flow, and hence $P_{\text{mus}}(\text{res})$, and instantaneous effort, i.e. total P_{mus} , is quite poor and, in fact, negative later in inspiration. An assist related to flow only, therefore, would amplify effort early in inspiration, where effort is small, while leaving the muscles essentially unsupported late in inspiration, where effort is greatest.

Similarly, because $P_{\text{mus}}(\text{el})$ constitutes a different fraction of total P_{mus} at different times of inspiration, volume is not a perfect correlate of effort, although, because both P_{mus} and volume rise during inspiration, the correlation is better than in the case of flow. Nonetheless, assist proportional to volume only would provide P_{mus} amplification primarily late in inspiration, but would leave the early part of inspiration essentially unsupported. This result would not be particularly adverse if resistance is normal since, in this case, the relation between effort and ventilatory consequences early in inspiration would be normal and not requiring support. However, since R is abnormal in all ventilated patients, at least because of the added resistance of the endotracheal tube and apparatus resistance, the failure of P_{mus} amplification early in inspiration would leave the patient with a sense of loading which may lead to respiratory distress. The patient's own resistance also may be high, although the increase in inspiratory airway resistance even with very severe obstructive diseases is only modest and the main load is still primarily elastic, as dictated by dynamic hyperinflation.

Another consideration regarding the use of support in proportion to either flow or volume alone is the fact that amplification of one component of P_{mus} , namely $P_{\text{mus}}(\text{el})$ or $P_{\text{mus}}(\text{res})$, inevitably results in an increase in the contribution of the other, unsupported, component. Thus assist in proportion to flow will initially increase flow. Lung volume, and hence elastic component of P_{mus} , rises at a faster rate. The contribution of $P_{\text{mus}}(\text{res})$, and hence the assist, must subsequently decline as a result.

It follows from this discussion that, in order to normalize the relation between effort and its ventilatory consequences, it is necessary to provide support to both flow and volume, according to equation (3) above. In this way, P_{mus} is amplified regardless of how it is partitioned between elastic and resistive components.

The illustration shown in Figure 7 also should not be interpreted as implying that the control should proceed in a sequential manner as illustrated. Analog control circuitry can function just as well. In both cases (digital and analog) the command signal to the pressure generator changes only subsequent to, and not in

advance of, a change in flow and volume thereby rendering the ventilator subservient to the patient and not the opposite.

For the delivery of PAV, motor driven bellows is the preferred basic design, since the relation between command signal and pressure output is more direct, as opposed to gas powered ventilators where pressure can be varied only by controlling flow. The relation between flow and system pressure is extremely complex. Delicate servo control would be essential and this would tend to cause oscillations in the PAV modality, unless severe filtering is applied which considerably dampens the response, as described above.

An embodiment shown in Figure 8, utilizing motor driven bellows, is suitable where the relation between power delivered to motor and pressure in the bellows is linear in the range of motion required for ventilation. This is achieved by mechanical design that minimizes inertial and resistive losses during movement of piston or bellows and by insuring that the motor operates in a linear range (i.e. fixed relation between power supply and force output) through the entire clinically-useful volume range of piston or bellows. The use of such mechanical design obviates the need for using pressure feedback and error signal to control the motor. As indicated earlier, the use of pressure feedback in the PAV modality destabilizes the device (because the desired pressure is not itself a fixed reference or function but is highly labile and influenced by the pressure in the system). Eliminating the pressure feedback from the command signal, therefore, results in a much more stable system. Filtering can be minimal with enhanced responsiveness of the device. The operation of such device then would be essentially errorless.

Figure 8 illustrates what currently is the best mode known to the applicant for carrying the invention (PAV) into effect. A low inertia, low resistance rolling seal piston 201 freely moves within a chamber 202. The chamber 202 receives gas through a one-way valve with an appropriate opening pressure level 203 during the exhalation phase while, during the inhalation phase, gas moves from the chamber 202 to patient 208 through another one-way valve 204. The piston 201 is coupled to the coil of a linear drive motor 205, which itself moves freely within a fixed magnet 206. The coil 205 pushes or pulls on the piston 201 in proportion to the magnitude of the drive potential supplied to the coil 205 via a cable 207. Clearly, any other type of bellows-motor combination would be suitable, provided that the requirement is satisfied that there is permitted a free flow of gas to the patient under a gradient generated by the patient. This requirement can be met either through the inherent mechanical properties (i.e. low inertia, low resistance) of the bellow-motor combinations or through appropriate servo-control of bellows position, as in prior art.

The rate of flow of gas from the chamber 202 to

the patient 208 is measured by a flow meter 209 mounted on the inhalation conduit 210. Alternatively, the rate of gas flow can be measured using a velocity transducer that monitors the rate of piston movement (not shown). The position of the piston 201 is also monitored using a potentiometer 211 or other appropriate device.

The flow signal is conditioned through an externally adjustable gain control 212. This is the equivalent of K_2 in equation 3 above. The amplification may be constant or variable to allow for non-linear behaviour of the pressure-flow relation of patient and/or external tubing. The flow signal is also integrated using an integrator 213 to provide a signal corresponding to instantaneous inhaled volume 214. The latter is also conditioned through an externally adjustable gain control 215. This is the equivalent of K_1 in equation 3 above and again may be constant or variable to allow for non-linear elastic properties of the respiratory system. The flow and volume signals 216, 217 are summed using a summing amplifier 218, to generate a composite output signal. The summing amplifier may also receive other inputs 219 to permit the unit to be operated in a non-proportional assist mode. These additional inputs are described below.

A switch mechanism 220 channels the output of the summing amplifier 218 to the motor 205 during the inhalation phase and the later part of the exhalation phase. During the early part of the exhalation, the switch 220 channels instead a constant negative voltage 221 to return the piston 201 to a preset location, as judged by the potentiometer signal 211. In either case, the command signal 222 is first suitably amplified using a power amplifier 223 and power supply 224.

An exhalation tube 225 and exhalation valve 226 insure gas flow from patient to the ambient atmosphere during the exhalation phase. Any of a variety of commercially available exhalation valves can be used. The exhalation valve 226 is opened or closed according to its valve control mechanism 228.

A differential pressure transducer 227 measures the pressure gradient between a point upstream and a point downstream from the one-way valve 204 that directs flow on the inhalation line 210. The downstream point is preferably as close as possible to the patient to enhance the sensitivity of the transducer 227 to flow, while the upstream point may be conveniently located at the chamber 202. The inhalation phase is defined as any time during which the pressure upstream is higher than the pressure at the point nearer the patient. The exhalation phase is when pressure on the patient side of the valve 204 is higher than in the chamber 202. The output of the differential transducer 227 is channeled to the exhalation valve control mechanism 228 and to the switching mechanism 220 for the motor drive 205. At transition from inhalation to exhalation, as defined by transducer 227

output, the integrator 213 is reset to return the volume signal 214 to zero, in preparation for the next cycle.

Other inputs 219 to the summing amplifier 218 may include any of a variety of functions. Two preferred functions are a constant voltage, to provide continuous positive airway pressure (CPAP) if desired, and an input designed to cancel out the effect of inhalation tube resistance. In the latter case, the output of the differential transducer 227 is channeled to the summing amplifier 218 after suitable amplification and rectification (positive gradients from chamber to patient only). In this fashion, the piston generates a positive pressure component that equals the pressure gradient between chamber and patient, thereby essentially eliminating the resistive effect of the tubing at all flow rates.

Other inputs 219 may also include back-up functions, for example repetitive ramp or square wave voltage vs time functions to insure ventilation in the event of apnea. Alternatively, through these other inputs, manufacturers may wish to add other types of conventional ventilation methods in machines that deliver PAV, so that these additional methods, for example, airway pressure release ventilation (APRV) or synchronized intermittent mandatory ventilation (SIMV) or pressure support (PS), may be used jointly or alternately with PAV.

At the beginning of the exhalation phase, the piston 201 retracts under the influence of the negative voltage 221, acquiring fresh gas of a desired composition through the one-way valve 203 until it reaches a preset level. The switching mechanism 220 then disconnects the negative voltage and channels the output of the summing amplifier 218 to the motor 205. At this point, the conditioned flow signal 216 is zero and the conditioned volume signal 217 is also zero as a result of integrator 213 resetting. The only drive is from other inputs 219. In the event a constant voltage is applied via other inputs 219, the motor 205 will pressurize the piston 201 to a constant level in preparation for the next inhalation. The level of constant pressure is typically set to be just below the level of desired positive end expiratory pressure (PEEP), as determined by the exhalation valve control or other suitable PEEP device. In this way, flow begins from chamber to patient as soon as airway pressure decreases below the PEEP level. Once flow begins, the output of the summing amplifier changes according to the sum of the conditioned flow 216 and volume 217 signals and the constant voltage, if any, via other inputs 219. This causes the pressure in the chamber 202 to rise. As discussed in detail above, so long as the gain factors for flow 212 and volume 215 are less than the values of resistance and patient elastance, the chamber pressure is not adequate by itself to entirely support the elastic recoil and resistive pressure losses and the patient is, therefore, contributing to the total pressure, and flow and volume remain res-

ponsive to patient effort. Once the patient terminates his own respiratory effort, there is accordingly not enough pressure to sustain the elastic recoil of the respiratory system. Pressure in the airway rises above chamber pressure and this, via the differential pressure transducer 227, causes the opening of the exhalation valve 226, resetting of the integrator 223 and hence loss of chamber pressure and the cycle is repeated.

In summary of this disclosure, the present invention provides a novel ventilation unit and ventilating procedure which are able to deliver air to a patient in proportion to patient ongoing inspiratory effort (Proportional Assist Ventilation, PAV). Modifications are possible within the scope of this invention.

Claims

1. A method for providing breathing assistance in proportion to patient ongoing inspiratory effort, characterized by the steps of (a) providing a free flow of gas from a gas delivery system to a patient in response to a pressure gradient generated by patient inspiratory effort; (b) determining the rate and volume of flow of said gas to said patient; (c) independently amplifying signals corresponding to said determined rate and volume of flow; and (d) providing a pressure assist to said gas in proportion to the sum of said determined and amplified rate and volume of flow.

2. The method claimed in claim 1, wherein said pressure assist is determined by the equation:

$$P_{vent} = K_1 V + K_2 \dot{V}$$

where P_{vent} is the magnitude of the pressure assist, K_1 is a gain factor applied to a variable ongoing volume signal V and K_2 is a gain factor applied to a variable ongoing flow-signal \dot{V} .

3. The method claimed in claim 2, wherein non-linear functions are employed in place of K_1 and K_2 .

4. The method claimed in claim 1, wherein said pressure assist is determined by the equation:

$$P_{vent} = A \cdot P_{mus}$$

where P_{vent} is the magnitude of the pressure assist, A is an independent factor which determines the proportionality between the pressure assist and patient generated pressure, and P_{mus} is the estimated instantaneous patient generated pressure determined by the equation:

$$P_{mus} = V \cdot E_{rs} + \dot{V} \cdot R_{rs} - P_{vent}$$

where V is the magnitude of the variable ongoing volume signal, \dot{V} is the magnitude of the variable ongoing flow signal, E_{rs} is the elastance of the respiratory system of the patient and R_{rs} is the resistance against which the respiratory system of

the patient is operating.

5. The method claimed in any one of claims 1 to 4, wherein said rate and volume of flow are determined by continuously sensing the movement of gas to the patient and generating an electrical signal corresponding in magnitude to each of the sensed rate and volume of gas, continuously separately amplifying each signal to a degree required to provide the pressure assist and providing a summed signal combining each of said amplified signals, and continuously applying said summed signal to said gas delivery system, thereby to provide said pressure assist.

6. The method claimed in claim 5, wherein said movement of gas is sensed to generate an electrical signal corresponding to the rate of flow of gas through a tube connecting said gas delivery system to the patient, and said electrical signal is integrated to provide a further electrical signal corresponding to the volume of flow through said tube.

7. The method claimed in any one of claims 1 to 6, wherein said gas delivery system comprises bellows means and an electrical motor operatively connected to said bellows means to generate a pressure corresponding in magnitude to the magnitude of the summed signal applied to said electrical motor.

8. The method claimed in any one of claims 1 to 7, wherein said gas delivery system develops negative pressure to assist patient's breathing through the application of negative pressure to a body surface of the patient.

9. The method claimed in any one of claims 1 to 8, when used in conjunction with a method of ventilatory assist employing a predetermined relationship of pressure, flow and/or volume versus time, including continuous positive airway pressure (CPAP), intermittent mandatory ventilation (IMV), pressure support ventilation (PSV), and airway pressure release ventilation (APRV).

10. Apparatus for delivering proportional assist ventilation to a patient, characterized by (a) means (202) for delivering a free flow of gas to a patient in response to patient inhalatory effort; (b) means (205) operatively connected to said gas delivery means (202) for generating pressure in said free flow of gas in response to an electrical command signal (207); (c) detection means (209) for detecting the instantaneous volume and rate of gas flow to the patient and for generating a separate electrical signal corresponding in magnitude to each

of said detected values; (d) means (212, 215) for selectively applying amplification to each of said electrical signals; and (e) means (218) for generating said electrical command signal (207) to said pressure generating means (205) in proportion to the sum of said amplified electrical signals corresponding in magnitude to said instantaneous rate and volume of flow.

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11. The apparatus claimed in claim 10, wherein said gas delivery means comprises bellows means (201) and said gas pressure generating means comprises an electrical drive motor (206) operatively connected to said bellows means (201).

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12. The apparatus claimed in claim 11, wherein said bellows means (201) comprises a rolling seal piston.

13. The apparatus claimed in any one of claims 10 to 12, wherein said detection means comprises flow rate sensing means (209) operatively connected to a pipe (210) joining said gas delivery means (202) to a patient for generating an electrical signal indicative of the rate of flow of gas through said pipe (210) and electrical circuit means (213) for generating an electrical signal indicative of volume flow through said pipe (210) from said electrical signal indicative of gas flow rate as said detected value of flow volume.

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14. The apparatus claimed in claim 13, wherein said means for generating an electrical command signal comprises summing means (218) for summing amplified electrical signals of said volume and gas flow rates, and including means (223) for applying said command signal to said electrical motor means, thereby to provide a ventilatory assist to said patient corresponding to the magnitude of said summed signal.

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15. The apparatus claimed in any one of claims 10 to 14 adapted to deliver ventilatory assist in the form of negative pressure intended for application to a body surface.

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16. The apparatus claimed in any one of claims 10 to 15, including electrical circuit means to override said means for generating said electrical command signal to provide an alternative command signal corresponding to an operator predetermined relationship of pressure, flow and/or volume versus time, including continuous positive airway pressure (CPAP), intermittent mandatory ventilation (IMV), pressure support ventilation (PSV), and airway pressure release ventilation (APRV).

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